



[7590-01-P]

NUCLEAR REGULATORY COMMISSION

[NRC-2017-0215]

Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres®

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft guidance; extension of comment period.

SUMMARY: On November 7, 2017, the U.S. Nuclear Regulatory Commission (NRC) solicited comments on its licensing guidance for licenses authorizing the use of Yttrium-90 (Y-90) Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres®. The public comment period was originally scheduled to close on January 8, 2018. The NRC has decided to extend the public comment period to allow more time for members of the public to develop and submit their comments.

DATES: The due date of comments requested in the document published on November 7, 2017 (82 FR 51655) is extended. Comments should be filed no later than February 8, 2018. Comments received after this date will be considered, if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov> and search for Docket ID NRC-2017-0215. Address questions about NRC dockets to Carol Gallagher; telephone: 301-415-3463; e-mail: Carol.Gallagher@nrc.gov. For technical

questions, contact the individual listed in the FOR FURTHER INFORMATION CONTACT section of this document.

- **Mail comments to:** May Ma, Office of Administration, Mail Stop: OWFN-2-A13, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

FOR FURTHER INFORMATION CONTACT: Lisa Dimmick, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-0694; e-mail: Lisa.Dimmick@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC-2017-0215 when contacting the NRC about the availability of information regarding this action. You may obtain publicly-available information related to this action by any of the following methods:

- **Federal rulemaking Web Site:** Go to <http://www.regulations.gov> and search for Docket ID NRC-2017-0215.

- **NRC's Agencywide Documents Access and Management System (ADAMS):** You may obtain publicly-available documents online in the ADAMS Public Documents collection at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "[ADAMS Public Documents](#)" and then select "[Begin Web-based ADAMS Search](#)." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr.resource@nrc.gov.

The draft Y-90 Microsphere Brachytherapy Sources and Devices Licensing Guidance, Revision 10, is available in ADAMS under Accession No. ML17107A375.

- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

The draft Y-90 Microsphere Brachytherapy Sources and Devices Licensing Guidance, Revision 10, is also available on the NRC's public Web site on the "Medical Uses Licensee Toolkit" page at <https://www.nrc.gov/materials/miau/med-use-toolkit.html>.

B. Submitting Comments

Please include Docket ID NRC-2017-0215 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at <http://www.regulations.gov> as well as enter the comment submissions into ADAMS. The NRC does not routinely edit submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submission into ADAMS.

I. Discussion.

On November 7, 2017, the NRC solicited comments on its draft licensing guidance entitled “Yttrium-90 (Y-90) Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® Licensing Guidance.” This draft would be revision 10 to this licensing guidance. The licensing guidance for Y-90 microsphere brachytherapy was initially published in October 2002 and subsequently revised in 2004, 2007, 2008, 2011, 2012, and 2016. Following years of using the current licensing guidance, the NRC staff, stakeholders, and the Advisory Committee on the Medical Uses of Isotopes identified numerous issues that need to be addressed. A working group composed of Agreement State representatives and NRC staff was formed to address identified issues. This draft licensing guidance for Y-90 microsphere brachytherapy has been revised to update criteria for training and experience, medical event reporting, inventory requirement specifications, and waste disposal issues. The draft guidance provides new information regarding cremation and autopsy. The public comment period was originally scheduled to close on January 8, 2018. The NRC has decided to extend the public comment period on this document until February 8, 2018, to allow more time for members of the public to submit their comments.

Dated at Rockville, Maryland, this 27th day of December 2017.

For the Nuclear Regulatory Commission.

Kevin Williams, Deputy Director,

Division of Material Safety, State, Tribal
and Rulemaking Programs,
Office of Nuclear Material Safety
and Safeguards.

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